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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,670	01/18/2005	Hideji Tajima	10287.65	2325
27683	7590	04/01/2010		
HAYNES AND BOONE, LLP			EXAMINER	
IP Section			POPA, ILEANA	
2323 Victory Avenue			ART UNIT	PAPER NUMBER
Suite 700				1633
Dallas, TX 75219				
		MAIL DATE	DELIVERY MODE	
		04/01/2010	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,670	Applicant(s) TAJIMA, HIDEJI
	Examiner ILEANA POPA	Art Unit 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 October 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4,5,8-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4, 5, 8-14 and 16-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. Claims 2, 3, 6, 7 and 15 have been cancelled. Claims 1 and 14 have been amended.

Claims 1, 4, 5, 8-14 and 16-20 are pending and under examination.

2. All rejections pertaining to claims 6 and 7 are moot because Applicant cancelled the claims in the reply filed on 10/29/2009.

The objection to claim 1 is withdrawn in response to Applicant's amendments to the claim filed on 10/29/2009.

Response to Arguments

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, 5, 8, 9, 12-14, and 16-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631).

Tajima teaches a pipette device for separating high molecular substances of interest (such as DNA), the device comprising a drawing/discharging section having a nozzle which connects to a detachable cylinder chip having an inlet/outlet, wherein the

cylinder chip is loaded with magnetic particles coupled to biotin or streptavidin (i.e., a carrier housing), wherein the drawing/discharging section draws fluid into the cylinder chip via the inlet/outlet and discharges the fluid out of the cylinder chip via the same inlet/outlet; the magnetic particles are held in a predetermined position due to a magnetic field and the cylinder chip comprises a small diameter section in contact with the fluid to be drawn, an intermediate diameter section which captures the magnetic particles, and a large diameter section (i.e., opening) detachably connected to the nozzle (claims 1, 2, 12, 14, 19, and 20) (column 3, lines 50-67, column 4, lines 22-30 and 59-67, column 5, lines 14-22, column 6, lines 17-67, column 7, lines 7-27, 65, and 67, column 8, lines 1-7, Fig. 7, claims 1, 3-5, and 9). Tajima teaches that the pipette device has a transferring section capable of transferring the carrier housing with respect to outside containers comprising different reagents (claims 1 and 16) (column 7, lines 37-48, column 8, lines 8-67). Tajima also teaches that the detachable chips can further contain filter tips capable of binding DNA, wherein the filter tips can contain silica filters i.e., porous glass (i.e., the pipette device contains a plurality of carrier kinds) (claims 5, 8 and 13) (column 4, lines 22-37, column 9, lines 33-40, column 13, lines 54-58, Fig. 7 and 13). Tajima et al. do not teach their magnetic particles having a size such that they are not capable to pass through the inlet/outlet (claims 1, 4, 9, 14, 17), nor do they teach their large diameter section as comprising a filter (claims 19 and 20). However, one of skill in the art would know to provide the large diameter section with a filter; one of skill in the art would be motivated to do so in order to avoid contaminating the pipette nozzle. With respect to the magnetic particles not being able to pass through the inlet-

outlet, one of skill in the art would be motivated to do such in order to avoid loss of magnetic beads (and therefore, loss of captured material). It is noted that by doing such, one of skill in the art would necessarily remove the carrier through the large diameter section (claim 18). With respect to the limitations of adhesion prevention section (claims 1, 9 and 14) such was common practice in the prior art; one of skill in the art would have known to use adhesion prevention and holding sections when needed.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant traversed the instant rejection on the grounds that there are at least two differences between the claimed subject matter and Tajima '631. Specifically the differences are:

- 1) Tajima '631 does not disclose a carrier that is sized or shaped so that the carrier cannot pass through the inlet/outlet, as required by claim 1; and
- 2) Tajima '631 does not disclose an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section, as required by amended claim 1.

Applicant argues that the differences between the claimed subject matter and Tajima '631 would not have been obvious to a person having ordinary skill in the art.

The modification of Tajima '631 to provide a carrier that is sized or shaped so that the carrier cannot pass through the inlet/outlet is not obvious because the

Art Unit: 1633

modification renders Tajima '631 unsatisfactory for its intended purpose (MPEP §2143.01(V)).

The Examiner asserts that it is obvious to modify Tajima '631 to provide a carrier that is sized or shaped so that the carrier cannot pass through the inlet/outlet, writing that: "[w]ith respect to the magnetic particles not being able to pass through the inlet-outlet, one of skill in the art would be motivated to do such in order to avoid loss of magnetic beads (and therefore, loss of captured material) (Office Action mailed April 29, 2009, page 4 lines 7-10). One intended purpose of the liquid processing method of Tajima '631 is to permit the magnetic particles G to pass through the inlet/outlet of the chip (or pipette) T4 during the pumping (sucking and/or discharging) of fluid through the inlet/outlet in order to at least:

- a. draw the magnetic particles G and a reaction liquid from a cell C4 through the inlet-outlet of the chip (or pipette) T4 and into the chip T4 to separate the magnetic particles G with DNA bonded thereto from the reaction liquid1;
- b. mix and agitate a restriction enzyme fluid and the magnetic particles G in the chip (or pipette) T4 and a cell C5 into which the inlet/outlet of the chip T4 extends2;
- c. mix and agitate a reagent and the magnetic particles G in the chip (or pipette) T4 and a cell C6 into which the inlet/outlet of the chip T4 extends3; and
- d. draw the magnetic particles G and a DNA solution from a cell through the inlet-outlet of the chip (or pipette) T4 and into the chip T4.4.

This intended purpose of the liquid processing method of Tajima '631 is destroyed and rendered unsatisfactory by the required modification of (1) providing that

the magnetic particles G are initially separated from the reaction liquid and disposed in the chip (or pipette) T4 and (2) reducing the diameter of the inlet/outlet of the chip (or pipette) T4 so that the magnetic particles G cannot pass through the inlet/outlet of the chip (or pipette) T4. Since the disclosure in a reference cannot be modified to render the disclosure unsatisfactory for its intended purpose, the rejection of claims 1, 4-9, 12-14 and 16-20 under 35 U.S.C. §103(a) over Tajima '631 is improper and should be withdrawn.

Applicant argues that the modification of Tajima '631 to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section is not obvious because the modification renders Tajima '631 unsatisfactory for its intended purpose. The Examiner asserts that it is obvious to modify Tajima '631 to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section, writing that:

[w]ith respect to the limitations in claims 6 [and] 7 ... one of ordinary skill in the art would have known to use the claimed adhesion prevention ... section[] when needed. Thus, the claimed invention was *prima facie* obvious at the time the invention was made (Office Action mailed April 29, 2009, page 4, lines 12-15). Another intended purpose of the liquid processing method of Tajima '631 is to adhere the magnetic particles G against the inner wall of the chip (or pipette) T4 in order to at least:

- a. separate the magnetic particles G with DNA bonded thereto from a reaction liquid by adhering the particles G to the inner wall of the chip C4 and discharging the reaction liquid into the cell C4;

- b. efficiently transfer the chip T4 and the magnetic particles G adhered to the inner wall thereof from the cell C4 to the cell C5 and initiate the pumping (sucking and discharging) through the inlet/outlet to mix and agitate a restriction enzyme fluid in the cell C5 with the magnetic particles G in both the cell C5 and the chip T4;
- c. separate the magnetic particles G from the restriction enzyme fluid by adhering the particles G to the inner wall of the chip C4 and discharging the restriction enzyme fluid into the cell C5; and
- d. efficiently transfer the chip T4 and the magnetic particles adhered to the inner wall thereof from the cell C5 to the cell C6 and initiate pumping (sucking and discharging) through the inlet/outlet to mix and agitate a reagent in the cell C6 with the magnetic particles G in both the cell C6 and the chip T4.

This intended purpose of the liquid processing method of Tajima '631 is destroyed and rendered unsatisfactory by the required modification of providing an adhesion prevention section for keeping the magnetic particles G from being adhered to the inner wall of the chip (or pipette) T4. Since the disclosure in a reference cannot be modified to render the disclosure unsatisfactory for its intended purpose, the rejection of claims 1, 4-9, 12-14 and 16-20 under 35 U.S.C. §103(a) over Tajima '631 is improper and should be withdrawn.

Applicant also argues that the modification of Tajima '631 to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section is not obvious because the modification improperly relies on the capabilities of one of ordinary skill in the art rather than articulated reasoning with

some rational underpinning. MPEP §2142 specifies that: [t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. m, m, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also KSR, 550 U.S. at, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). The Examiner has not provided any articulated reasoning with some rational underpinning to modify Tajima '631 to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section, as required by MPEP §2142. Instead, the Examiner improperly relies on the capabilities of one of ordinary skill in the art as the alleged reason to modify Tajima '631 without providing any facts to support the Examiner's conclusory statements. This improper reliance is directly prohibited by MPEP §2143.01(IV), which provides that: [the] fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness.

Since the Examiner has not provided any articulated reasoning with some rational underpinning to modify Tajima '631 to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing

Art Unit: 1633

section, the rejection of claims 1, 4-9, 12-14 and 16-20 under 35 U.S.C. §103(a) over Tajima '631 is improper and should be withdrawn.

Moreover, it is not appropriate for the Examiner to take official notice of facts without citing a prior art reference where the facts are asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. See, e.g., MPEP 2144.03 and In re Ahlert, 424 F.2d at 1091.

Applicant requests that the Examiner either: (1) demonstrate that, at the time of the invention, providing an adhesion prevention section for keeping the magnetic particles G from being adhered to the inner wall of the chip (or pipette) T4, is capable of instant and unquestionable demonstration; or (2) provide a declaration pursuant to 37 C.F.R. § 1.104(d)(2) that details the personal knowledge of the Examiner as to providing, at the time of the invention, an adhesion prevention section for keeping the magnetic particles G from being adhered to the inner wall of the chip (or pipette) T4. In the absence of some documentary evidence supporting the Examiner's conclusory statement regarding the capabilities of one of ordinary skill in the art, the rejection of claims 1, 4-9, 12-14 and 16-20 under 35 U.S.C. §103(a) is improper and should be withdrawn.

Applicant's arguments are acknowledged; however, the rejection is maintained for the following reasons:

The only difference between Tajima and the instant invention is that Tajima uses smaller magnetic particles which able to pass through the microtip outlet (i.e., batch

Art Unit: 1633

purification), while the instant invention uses larger magnetic particles which are not able to pass through the microtip outlet (i.e., the instant invention uses the microtips as miniaffinity columns). Modifying Tajima by using larger magnetic particles would have been obvious to one of skill in the art (see the rejection above). The argument that doing such would render Tajima unsatisfactory for its intended purpose is not found persuasive. The principle of operation in Tajima is not passing the magnetic beads through the inlet/outlet, as Applicant argues, but rather affinity chromatography to purify macromolecules such as DNA; using small or large beads would not change the principle of operation. It was common knowledge in the prior art that separation by affinity chromatography could be achieved either in batch (Tajima) or by using columns or minicolumns packed with beads, wherein the minicolumns could be pipette tips and wherein beads larger than the column outlet are used to keep them inside the column (proposed modification) (see Kussmann-Gerber et al., Analytical Biochemistry, 1999, 271: 102-105; p. 102, column 1; p. 103, Fig. 1 and paragraph bridging p. 103 and 104; Posewitz et al., Anal. Chem., 1999, 71: 2883-1892, p. 2884, column 2, first full paragraph, p. 2885, column 1, fourth paragraph; Rush et al., U.S. Patent No. 7,198,896, column 16, lines 9-30; Gatlin et al., Anal. Biochem., 1998, 263: 93-101, p. 97, paragraph bridging columns 1 and 2). Based on the teachings in the art as a whole, one of skill in the art would have known that using either small or large magnetic would render the same result and would have found it obvious to use larger magnetic beads to achieve the predictable result of purifying macromolecules. Applicant did not provide any evidence to the contrary.

Applicant argues that modifying Tajima to provide an adhesion prevention section for keeping the carrier from being adhered to the inner wall of the carrier housing section renders Tajima unsatisfactory for its intended purpose. This is not found persuasive. Providing an adhesion prevention section (i.e. to prevent the adherence of the magnetic beads in the absence of an applied magnetic field) would not impede the magnetic particles to be attracted to the wall when the magnetic field is applied. Applicant did not provide any evidence to the contrary.

Applicant argues that it is not appropriate for the Examiner to take official notice of facts without citing a prior art reference because the facts are asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. This is just an argument not supported by any evidence. Providing carrier holding section to keep the carrier from adhering to the bottom and obstruct the flow was routine in the prior art (see August et al., U.S. Patent No. 6,530,288, Abstract, column 1, line 66 through column 2, line 34). Clearly, at the time the invention was made, it would have been within the knowledge and capabilities of one of skill in the art to improve the flow by using such inner wall structures.

For the reasons set forth above, Applicant's arguments are not found persuasive and the rejection is maintained.

5. Claims 1, 4, 5, 8-14, and 16-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631), in view of both Tajima (U.S. Patent No. 5,919,706) and Tajima (U.S. Patent No. 6,100,079).

The teachings of Tajima '631 are applied as above for claims 1, 4, 5, 8, 9, 12-14, and 16-20. Although Tajima '631 teaches their device as useful for separating high molecular substances of interest, he does not specifically teach monitoring separation by using a translucent chip (i.e., a translucent carrier housing) and an outside apparatus for measuring luminescence on the carrier (claims 10 and 11). However, doing such is suggested by the prior art. For example, Tajima '079 teaches that pipette devices such as the ones disclosed by Tajima '631 can be used to monitor the binding of high molecular substances of interest to magnetic beads, wherein monitoring takes place via luminescence (column 5, lines 40-54; column 7, lines 53-65). Although Tajima '079 does not specifically disclose translucent chips and an outside measuring apparatus, using such is taught by the prior art (see Tajima '706, column 3, lines 44-50; column 7, lines 34-45). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the device of Tajima '631, according to the teachings of Tajima '079 and Tajima '706, to achieve the predictable result of monitoring the separation of the macromolecule of interest. With respect to the limitation of the carrier housing having a side face made in a plane (claim 11), one of skill in the art would know to modify the chip (i.e., the carrier housing) according to the measuring equipment used. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant's arguments regarding Tajima '631 are the same as above. Applicant argues that Tajima '706 discloses a liquid processing method but does not disclose the

differences between claim 1 and Tajima '631. Tajima '079 discloses a method for treating biopolymers but does not disclose the differences between claim 1 and Tajima '631. Claims 10 and 11 depend from and include the subject matter of claim 1. Since neither Tajima '706 nor Tajima '079 discloses the differences between claim 1 and Tajima '631, it is clear that the combination of Tajima '631, Tajima '706 and Tajima '079 does not disclose the subject matter of claim 1 and of claims 10 and 11 which depend therefrom. In addition, it would not be obvious to modify the disclosures of Tajima '631, Tajima '706 and Tajima '079 to include the subject matter of any of claims 1, 4, 5, 8-14 and 16-20 because there is no reason to so modify the disclosures.

Applicant's arguments are acknowledged; however, the rejection is maintained for the following reasons:

Regarding Tajima '631, see above. For the reasons set forth above, Tajima '706 and Tajima '079 do not have to disclose the differences between claim 1 and Tajima '631. Applicant's argument that it would not be obvious to combine Tajima '631, Tajima '706 and Tajima '079 is not found persuasive because it is just an argument not supported by any evidence.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kussmann-Gerber et al. (Analytical Biochemistry, 1999, 271: 102-105), Posewitz et al. (Anal. Chem., 1999, 71: 2883-1892), Rush et al. (U.S. Patent No. 7,198,896) and Gatlin et al. (Anal. Biochem., 1998, 263: 93-101) were cited in response to Applicant's arguments that the proposed modification of Tajima '631 would not have been obvious to one of skill in the art. Specifically, the references provide evidence that using microtips as microcolumns for affinity chromatography (i.e., the proposed modification) was routine in the prior art.

August et al. (U.S. Patent No. 6,530,288) provide evidence that the use of carrier holding sections to keep the carrier from adhering to the column bottom was routine in the prior art.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Primary Examiner, Art Unit 1633